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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,980	12/09/2003	George Chin-Sheng Chou	BHT/3092-397	2232

7590 10/14/2005

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EXAMINER

SWARTZ, RODNEY P

ART UNIT PAPER NUMBER

1645

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/729,980

Applicant(s)

CHOU ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The examiner notes that the Office Actions, mailed 18 November 2004 and 2 March 2005, were in error in the number of claims pending. Claim 19 appeared at the end of claim 18. Therefore, there were actually 20 claims pending. Applicants' Response to Office Action, received 2 August 2005, is acknowledged. Claims 1, 2, 5, 11-15, 18-20 have been amended.
2. Claims 1-20 are pending. Claims 8-10 and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.
3. Claims 1-7 and 11-14 are under consideration.

### **Rejections/Objections Withdrawn**

4. The objection to claim 1 is withdrawn in light of the amendment of the claim.
5. The objection to claim 2 is withdrawn in light of the amendment of the claim.
6. The objection to claim 11 is withdrawn in light of the amendment of the claim.
7. The objection to claim 13 is withdrawn in light of the amendment of the claim.
8. The rejection of claim 13 under 35 U.S.C. 112, second paragraph, indefiniteness for "derivative", is withdrawn in light of the amendment of the claim.
9. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, lack of antecedent basis for "tubes" in steps b and c, is withdrawn in light of the amendment of the claims.
10. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, indefiniteness for identity of magnetic beads, is withdrawn in light of the amendment of the claims.

### **Rejections/Objections Maintained**

11. The rejection of claims 11-14 under 35 U.S.C. 112, first paragraph, scope of enablement for kit for detecting microorganism cDNA comprising any/all other identified probes linked to magnetic bead, is maintained for reasons of record as now applied to a "system".

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Applicants argue that the amendment of the claim to recite "system" instead of "kit" obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. Merely changing the name from "diagnostic kit" to "system" does not correct the insufficiency of the enablement support for the claims. As stated in the original rejection, the specification indicates that identification of microorganism cDNA is possible if one utilizes microorganism-specific probes which actually hybridize to microorganism DNA. The instant claims recite no such microorganism-specific probes which actually hybridize to microorganism DNA, merely "a probe" linked to a magnetic bead. Thus, the scope of the instant claims, i.e., any/all nonmicroorganism-specific probes, constitute merely an invitation to experiment without a reasonable expectation of success.

12. The rejection of claims 1-7 under 35 U.S.C. 112, second paragraph, incomplete for omitting essential elements, is maintained for reasons of record.

Applicants state that the amendment of the claims obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. Newly amended claim 1 does not recite any comparison to a background, i.e., control sample. Claim 1 recites merely "detecting a color change utilizing a luminescence-emission substrate". This means that any change in the indicator is a positive result. This contradicts the teachings in the specification, page 15, which indicates that a specific level of luminescence is required for a positive result.

13. The provisional rejection of claim 2 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending application No. 10/833,097, is maintained for reasons of record.

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Applicants refer in their argument to copending application no. 29/200,803. Clarification is required because the present rejection does not recite this application number.

Because there are other rejection remaining in this application, this rejection is maintained until such time as all other rejections are withdrawn or a Terminal Disclaimer is submitted.

### **New Rejection Necessitated by Amendment**

#### **Claim Rejections - 35 USC § 112**

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Newly amended claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, lack of antecedent basis.

Newly amended claim 1, step (d) now recites the limitation, into the "tube", connoting adding enzyme complex to only one tube. There is insufficient antecedent basis for this limitation in the claim because amended steps a, and steps b-c recite multiple "tubes", e.g., step c, "add blocking solution into the **tubes**". This connotes adding blocking solution into each of the tubes.

### **Conclusion**

16. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of

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the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. This application contains claims 8-10 and 15-20 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

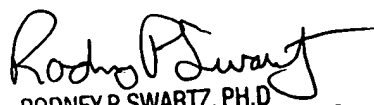
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST. If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER

October 10, 2005